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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,161	08/24/2001	Richard W. Voellmy		4118

7590

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/939,161

**Applicant(s)**

VOELLMY, RICHARD W.

**Examiner**

Simon J. Oh

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-20 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-20 and 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, and request for continued examination, all received on 23 September 2004.

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-15, 21, and 22 under 35 U.S.C. 112, first paragraph, for lack of enablement, is rendered moot with the cancellation of those claims.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-15, 21, and 22 under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* in view of Jimenez *et al.* is rendered moot with the cancellation of those claims.

The rejection of Claims 16-20 under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* in view of Jimenez *et al.* is maintained.

Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* (U.S. Patent No. 5,830,177) in view of Jimenez *et al.* (U.S. Patent No. 5,486,509)

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The Li *et al.* patent teaches compositions and treatment methods useful for the prevention of hair loss during chemotherapy. In a preferred embodiment, a nucleic acid comprising an expression vector capable of expressing human p-glycoprotein is administered to a subject (See Column 4, Lines 39-62). Methods of administration include the use of various carriers and incorporation into liposomes (See Column 5, Lines 16-23). Other methods of administration also include the utilization of electromagnetic radiation, including infrared radiation (See Column 5, Lines 58-66).

Li *et al.* does not teach the administration of a method of treatment for the prevention of chemotherapy-induced alopecia between 2 and 24 hours before administration of a chemotherapeutic drug.

Jiminez *et al.* teaches methods of inhibiting chemotherapy-induced alopecia (See Abstract). Compositions to be used with the treatment may include various carriers, diluents, and excipients, as well as penetration enhancing agents (See Column 3, Lines 43-52; and Column 4, Lines 1-8). Treatments for the prevention of chemotherapy-induced alopecia preferably administered once or twice daily beginning 5 to 8 days prior to the administration of a chemotherapeutic agent (See Column 4, Lines 13-31; and Examples).

It would be obvious to one of ordinary skill in the art to combine the teachings of Li *et al.* and Jiminez *et al.* into the objects of inventions of the rejected claims. One of ordinary skill would be motivated to combine the disclosures of the Jiminez *et al.* with those of Li *et al.* because one of ordinary skill in the art would seek to give a treatment subject sufficient time to build up a resistance to chemotherapy-induced alopecia before the administration of any

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chemotherapeutic drugs. To one of ordinary skill in the art, it would be expected that without this preparation time, such a method of preventing alopecia might be insufficient.

Thus, the instantly claimed invention is *prima facie* obvious.

### ***Response to Arguments***

Applicant's arguments filed 23 September 2004 have been fully considered but they are not persuasive.

The applicant's arguments appear to be based upon a narrow interpretation of both the claims and the prior art. The examiner would like to respectfully point out that the Li *et al.* patent discloses the steps of using various forms of electromagnetic radiation, including infrared radiation, in the treatment methods described therein. As such, the examiner interprets this disclosure as broadly reading on the applicant's recited method step of administering a heat dose. All pending claims will remain rejected.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1615

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